Secta. II-27—100.000—[illegible]

E. + P.H (1948) Department

4s. SERIES.

G.O. No. 2164 P.H

10

Dated 25-6-48.

[Despatch Abstract.]

DRUGS - The Madras Drugs Rules, 1945 - Provisions relating to Bacteriophages - Amendments -Issued.

No.F.18-1/46-D
Government of India,
Ministry of Health.

New Delhi, the 12th June , 1948.

From
J.N. Saksena, Esq., B.A.,
Assistant Secretary to the Government of India,
To
The Secretary to the Government of Madras,
Education and Public Health Department, Madras.

Subject:- Amendments to Drugs Rules, 1945 -
Provisions relating to Bacteriophages.

Sir,

I am directed to refer to the late Department of Health (India)'s letter No.18-1/46-D, dated the 28th July, 1947 and to say that in view of the latest recommendations of the Drugs Technical Advisory Board at their seventh meeting (extract enclosed for ready reference) it is not necessary to include any provisions for penicillin in the Drugs Rules (Central and Provincial). It is accordingly proposed to issue the amendments to the Drugs Rules, 1945 relating to Bacteriophages alone as in the attached draft notification in the issue of the Gazette of India dated the 26th June, 1948. It is requested that the Provincial Government may be moved to issue similar amendments to the Provincial Drugs Rules in the Provincial Gazette on or about the same date and a copy of these amendments supplied to this Ministry for information.

I have the honour to be,
Sir,
Your most obedient servant,
(Sd.) J.N.Saksena,
Assistant Secretary.

Extract taken from the Minutes of the seventh meeting of the D.T.A.B. (held on 19th and 20th January, 1948).

---

10. "The Board recommended that there was no need for including separate provisions for penicillin under Schedule 'F' to the Drugs Rules as detailed provisions had already been included in the U.S.P. XIII and the new edition of B.P. under issue.

GOVERNMENT OF MADRAS
Education and Public Health Department.
***

G.O.Ms.No.2167, Public Health D/25-6-1948.

ABSTRACT.

DRUGS - The Madras Drugs Rules, 1945 - Provisions relating to Bacteriophages - Amendments - Issued -
x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.x.
READ:-

G.O.2495, Public Health dated 22-8-1946.
No. 44854/48 From the Govt. of India, No.F18-1/46-D, d/12-6-1948.

O R D E R:

The following notification will be published in an extraordinary issue of the Fort St. George Gazette on the 26th June 1948:-

Notification.

In exercise of the powers conferred by section 33 of the Drugs Act, 1940 (Central XXIII of 1940) His Excellency the Governor of Madras hereby makes the following amendments in the Madras Drugs Rules, 1945:-

Amendment

I. In the said Rules--

(1) In the first proviso to rule 44,

(a) for the words, figures, letters and brackets "7 and 11 in Schedule C and those in Schedule C(1)" the figures, words and letter "7, 11 and 14 in schedule C" shall be substituted;

(b) for the words, figures, letters and brackets "7 and 11 in schedule C and those in Schedule C(1)" the figures, words and letter "7, 11 and 14 in Schedule C" shall be substituted;

(2) In rule 114, the word "and" occurred at the end of clause (g) shall be omitted, and after clause (h), the following clause shall be inserted, namely:-

"(i) preparations from cultures of pathogenic organisms in a form to be administered orally, which must be sterile."

II. In the Schedules annexed to the said Rules,

(1) In Schedule C, after the entry "13. Sterilised surgical ligature and Sterilised Surgical suture" the entry "14. Bacteriophages" shall be added.--

(2) In Schedule F

(i) Parts XI and XII shall be renumbered as Parts XII and XIII respectively; and

(ii) after Part X the following be inserted, namely:-

"Part XI.--Provisions applicable to the Production of Bacteriophages:

1. Definition:

(i) This part of this Schedule applies to the bacteriophages made from any micro-organism pathogenic to man or other animal.

(ii) For the purpose of this part of the Schedule, a bacteriophage means a sterile preparation derived from a culture of the micro-organism from which the bacteriophage derives its name.

2. Staff of establishment:

Any establishment where bacteriophages are prepared must be under the complete direction and control of a competent expert in bacteriology, who must be assisted by a staff adequate for carrying out the tests required during the preparation of the bacteriophages and in connection with the finished products.

3. Proper name:

The proper name of any bacteriophage shall be the word 'Bacteriophage' followed by the name of the micro-organism from which it is prepared, or other name approved by the licensing authority.

4. Records:

Cultures used in the preparation of bacteriophage must before being manipulated into a bacteriophage be identified by the generally accepted tests applicable to the particular micro-organism. The permanent records which

contd:-

GOVERNMENT OF MADRAS
Education & Public Health Department
***

Memorandum No.44586.G1/48-2.P.H., dated 25th June

Drugs - The Madras Drugs Rules, 1945 - Provisions relating to Bacteriophages - Amendments - Issued Publication of Notification -.

A copy of the Notification on the subject mentioned above is forwarded to the Superintendent, Government Press and he is requested to arrange for the publication of the notification in an Extra-ordinary issue of the Fort St. George Gazette on 26th June 1948. without fail.

(Sd.)xxxx,
Secretary to Government.

To
The Superintendent, Government Press.
(with a copy of notification).

(To be published in Part I, Section I of the Gazette of India, dated the 26th June, 1948).

No.F.18-1/46-D
Government of India,
Ministry of Health.

New Delhi, the June, 1948.

DRAFT NOTIFICATION.

In exercise of the powers conferred by sections 12 and 33 of the Drugs Act, 1940 (XXIII of 1940), the Central Government is pleased to direct that the following further amendments shall be made in the Drugs Rules, 1945, the same having been previously published as required by the said sections namely:-

I. In the said Rules

(1) In the first proviso to rule 44,

(a) for the words, figures, letters and brackets "7 and 11 of Schedule C and those in Schedule C(1)" the figures, words and letter "7, 11 and 14 in Schedule C" shall be substituted;

(b) for the words, figures, letters and brackets "7 and 11 of Schedule C and those in Schedule C(1)" the figures, words and letter "7, 11 and 14 in Schedule C" shall be substituted;

(2) In rule 114, after clause (h) the following clause shall be inserted, namely:-

"(i) preparations from cultures of pathogenic organisms in a form to be administered orally, which must be sterile."

II. In the Schedules annexed to the said Rules, --

(1) In Schedule C, after the entry "13. Sterilised surgical ligature and sterilised surgical Suture" the entr "14. Bacteriophages" shall be added.

(2) In Schedule F - ---

(i) Parts XI and XII shall be renumbered as Parts XII and XIII respectively; and

(ii) after part X the following shall be instered namely:-

"PART XI. -PROVISIONS APPLICABLE TO THE PRODUCTION OF BACTERIOPHAGES

1. Definition:

(i) This part of this Schedule applies to the bacteriophages made from any micro-organism pathogenic to man or other animal.

(ii) For the purpose of this part of this schedule a bacteriophage means a sterile preparation derived from a culture of the micro-organism from which the bacteriophage drives its name.

2. Staff of establishment:

Any establishment where bacteriophages are prepared must be under the complete direction and control of a competent expert in bacteriology, who must be assisted by a staff adequte for carrying out the tests required during the preparation of the bacteriophages and in connection with the finished products.

3. Proper name: The proper name of any bacteriophage /p.t.o

shall be the word 'Bacteriophage' followed by the name of the micro-organism from which it is prepared, or other name approved by the licensing authority.

4. Records.

Cultures used inthe preparation of bacteriophage must before being manipulated into a bacteriophage be identified by the generally accepted tests applicable to the particular micro-organism. The permanent records which the licensee is required to keep shall include a record of the origin, properties and characteristics of the cultures.

5. Combined bacteriophages:-

Bacteriophages may be issued either singly or combined in the same container. In the case of combinations of bacteriophage a name for the combined bacteriophage may be submitted by the licensee to the licensing authority and, if approved, may be used as a proper name of the bacteriophage.

6. Containers:-

The container shall be sealed glass ampoule of non-alkaline resistance glass.

7. LABELLING.

The label of the container shall indicate:

(a) The proper name of the bacteriophage;

(b) The words 'For oral administration only';

(c) The date of manufacture; and

(d) A caution to the effect that if the preparation is cloudy or shows a deposit it should be discarded.

8. Tests:

Bacteriophages shall be subjected to the same tests for sterility as prescribed in these rules for bacterial vaccines."

which the licensee is required to keep shall include a record of the origin, properties and characteristics of the cultures.

5. Combined bacteriophages:- Bacteriophages may be issued either singly or combined in the same container. In the case of combinations of bacteriophage a name for the combined bacteriophage may be submitted by the licensee to the licensing authority and, if approved, may be used as a proper name of the bacteriophage.

6. Containers: The container shall be a sealed galss ampoule of non-alkaline resistance glass.

7. Labelling: The label of the container shall indicate:

(a) The proper name of the bacteriophage;

(b) the words 'For oral administrat~~ive~~ion only';

(c) the date of manufacture;and the preparation is cloudy or shows a deposit it should be discarded.

8. Tests: Bacteriophages shall be subjected to the same tests for sterility as prescribed in these rules for bacterial vaccines."

and a caution to the effect that the

Date:26-6-1948.

SPECIAL.(Very urgent.)

From: The Supdt. , Govt. Press: To J.S., E & P.H.

1. An amendment to Madras Drug Rules re. bacterias, plagues, has been asked to be published to day in a Gazette--Extraordinary From the contents of the amendments I am doubtful whether the expenditure ~~incurred~~ involved in the issue of a gazette extraordinary expecially on a saturday which invovles working overtime is justified. Its publications in regular issue of the Fort St. George Gazette next tuesday appears to be sufficient.

~~I-f1-~~ If you still consider it essential to publish it as a Gazette Extraordinary, please communicate by phone before 1P. The personal sanction of the Secretary, E & P.H. Dept. I would also request that the occasion for the issue of Gazette Extraordinary be restricted to cases when a few days delay will result in serious administrative difficulty.

EDUCATION & P.H. DEPARTMENT(G

From
The Deputy Secretary,

To
The Superintendent, Government Press.

Reference your telephonic message of to-day regarding the issue of a Gazette Ex-traordinary in respect of amendments to the Madras Drugs Rules -

---

It is sufficient if the notification contained in G.O. No.2167 Public Health dated the 25th June 1948 is published in the ordinary issue of the Fort St. George Gazette on the 29th June 1948 without fail.

(Sd.) T.G.M.
26-6-1948.

/TRUE COPY/

Superintendent,
Madras Record Office.

***